United Kingdom Jobs Expertini®

Quality Assurance Software Validation Specialist

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Company: CooperCompanies

Location: United Kingdom

Category: computer-and-mathematical

JOB TITLE : Quality Assurance Software Validation Specialist

LOCATION: Southampton (Mount Park)

WORKING HOURS : Monday to Friday 37.5 hours per week – Hybrid 2 days office/3 days home depending on business need

A brighter future awaits you

At CooperVision, we are proud to be the global leader in contact lenses. At our innovative sites worldwide, we manufacture and distribute contact lenses to some of the biggest names in optics. We're all about creating brighter futures for our customers, our wearers and our people.

What can you expect from us as an employer?

Well, we like to look at things a little differently. We call it bringing a refreshing perspective. And for every one of us who works here, it means our opinion really counts, we get to share our ideas, and we get to make an impact.

We're big on belonging. Because being part of something great is what makes our company the best it can be. And we value diversity, because you can see a whole lot more when you have different perspectives. We're an ambitious company. And to help us achieve our goals, we'll give you all you need to achieve yours.

What will you be doing?

We have a fantastic opportunity for someone to join our Global Quality Assurance Operations team as a Quality Assurance Software Validation Specialist. You will be working with our Regulatory Affairs and Quality Assurance (RAQA) teamto provide support and coordination

to functional areas of Global IT with Computer Systems Validation (CSV). There will be opportunities to liaise with local (country specific) IT on the implementation of new systems and upgrades to existing systems.

You will work closely with IT infrastructure groups on changes for GxP Regulated systems as well as Implement and maintain global CSV Policies and procedures along with IT personnel training and training records.

There will be responsibility for the global validation activities for enterprise information systems. Primary responsibilities include supporting the implementation of new systems, ensuring these systems adhere to the regulations and maintain CooperVision's computer systems are in a validated state.

Essential responsibilities:

Responsible for drafting or co-ordinating the draft of computer system validation documentation including computer systems validation (CSV) plans, risk assessments, test scripts, data migration plans/reports, traceability matrix and summary reports that are required for validation audits.

Provides input to development of corporate standards, policies and standard operating procedures (SOPs) for Information Systems

Provide technical guidance to the Compliance team members on change management current methods and processes

Works closely with other compliance analysts and internal audit on harmonizing control requirements and frameworks

Trains and mentors project team personnel (developers, testers, business systems analysts) at company level in computer system lifecycle methodology

Provides guidance with functional/ end user requirements, compliance and system specifications, and ensures that proper documentation is maintained

Responsible for providing guidance in planning, implementing, and documenting user acceptance testing

Responsible for test execution training and assists teams with the discrepancy (defect) management

Analyses formal test results in order to identify weaknesses/failures in control performance and documentation

Reviews requirements traceability matrices for completeness of appropriate documentation and testing for user specific requirements

Ensures compliance with internal and external computer system lifecycle policies and regulations

Performs periodic reviews and remediation activities on validated systems

Oversees small projects and/or tasks and phases of larger projects. Responsible for coordinating activities of teams, schedules and resources for assigned tasks or projects

Responsible for maintaining the current system inventory listing

Interacts with auditors (FDA, SOX) to provide necessary documentation during audits.

What are we looking for?

Experience/exposure in Software Quality Assurance and Computer System Validation and Requirements Analysis.

Familiar with Systems Delivery/Development Lifecycle Management (SDLC) and Change Management methodologies and frameworks.

Awareness of Medical device regulations such as FDA 21 CFR Part 11, Part 820, SOX and ISO3485, with good understanding of GxP related processes including risk-based approach and validation

Experience with automated systems for the following activities/functions would be helpful but not essential -Enterprise Resource Planning (Oracle E Business Suite),Document management (Oracle Agile/SharePoint),Requirements and Testing (HP ALM/HPQC/JIRA), Change/Incident Management (ServiceNow/Remedy),Project/Task Management (Innotas/Microsoft project)

Experience of working as part of a QA team within a regulated industry

Good and clear communicator with strong presentation skills

Must be proficient with Microsoft Office

What do we offer?

You'll receive competitive compensation and a fantastic benefits package including; 25 days holiday, pension scheme, healthcare cover, life assurance, access to our Wellness Platform to support you in mental health and wellbeing, a discounted contact lens scheme and much more!

What is important to us?

Our four values define and underpin our unique culture; we are dedicated, we are inventive, we are friendly, and we are partners. Becoming part of the CooperVision family means joining a friendly team that's open, flexible, and respectful of each other's differences, working together to achieve something amazing.

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